CLINICAL CAPSULES

Periodontitis Linked to HT

For the first time, periodontal disease has been linked with renal insufficiency and its attendant hypertension in a communitybased study of atherosclerosis risk.

Noting that periodontitis has been linked to both cardiovascular and cerebrovascular disease, Abhijit V. Kshirsagar, M.D., and his associates at the University of North Carolina, Chapel Hill, assessed whether it might also be linked to chronic kidney disease, which has similar risk factors, including inflammation. In their study of 5,537 middle-aged adults residing in four U.S. communities, 41% were found to have early periodontitis, 17% had severe periodontitis, and the rest had healthy gums (Am. J. Kidney Dis. 2005;45:650-7).

Those with either early or severe dental disease were twice as likely as were the others to have impaired renal function and its attendant hypertension.

Combining CABG and Endarterectomy

Performing carotid endarterectomy at the same time as coronary artery bypass grafting (CABG) to head off a potential stroke actually seems to raise the risk of stroke, reported Michael D. Hill, M.D., of the University of Calgary (Alta.), and his associates. CABG candidates who have severe carotid stenosis are at increased risk of stroke as a complication of the procedure, compared with those without stenosis. Many centers now offer combined carotid endarterectomy and CABG procedures for such patients, in the hope of preventing this complication from arising. Some do the combined procedures routinely, even for patients with milder carotid stenosis, even though "it is not clearly known whether this is appropriate," the investigators noted (Neurology 2005;64:1435-7).

In their study of 131,762 patients who

underwent CABG in Canada during 1992-2001, including 669 who had simultaneous CABG plus carotid endarterectomy, the rate of stroke or death was nearly three times higher in the combined-procedure group (13.0%) than in the CABG-only group (4.9%). Yet utilization of the combined procedure rose steadily over the 9year study period, increasing by as much as sevenfold in some areas.

In an editorial, Patrick Pullicino, M.D., of New Jersey Medical School, Newark, and Jonathan Halperin, M.D., of Mount Sinai Medical Center, New York, said, "The onus is now on surgeons who perform [carotid endarterectomy plus CABG] to show that it can be performed with acceptable risks" (Neurology 2005;64:1332-3).

Preinfarction Angina May Be Good Sign

Transient angina in the 24 hours before onset of MI appears to be associated with limited infarct size, preservation of myocardial viability, and preservation of left ventricular function, reported Ignacio Iglesias-Garriz, M.D., and his associates at Hospital de León (Spain).

Positive outcomes following so-called preinfarction angina (PA) have been noted in many studies. Dr. Iglesias-Garriz and his associates examined this link in a study of 78 patients with ST-segment elevation acute MI who underwent primary coronary intervention; 32 of them had experienced typical transient chest pain at rest in the day preceding the infarct (Chest 2005;127:1116-21).

Those with PA had smaller infarct size, with a mean percentage of necrotic left ventricle of 18.0%, compared with 27.0% for those who had no PA. Those with PA also had a higher rate of ST-segment resolution (65.6% vs. 45.7%) and a lower incidence of left ventricular systolic dysfunction (3.2% vs. 18.6%).

These favorable findings are probably due to "a better myocardial tissue perfusion if PA is present," the researchers said. It is also possible that angina "triggers an intracellular signal that intrinsically preserves cells from death," they added.

Homocysteine, AV Fistula Thrombosis

High homocysteine levels predict which hemodialysis patients are likely to develop thrombosis of the native arteriovenous fistula that allows vascular access for the procedure, reported Francesca Mallamaci, M.D., of the Institute of Biomedicine, Calabria, Italy, and her associates.

In what they described as the first prospective cohort study to show a direct link between hyperhomocysteinemia and vascular access failure, the researchers followed 205 hemodialysis patients with native AV fistulas in either the upper or the lower arm for a mean of 32 months. The 78 patients who developed one or more vascular access thromboses had significantly higher homocysteine levels (3.91 mg/L) than did patients without thromboses (3.45 mg/L). The relative risk for thrombotic events was nearly twice as high in the onethird of patients with the highest homocysteine levels than in the one-third who had the lowest levels (Am. J. Kidney Dis. 2005;45:702-7). Further study should examine whether reducing homocysteine levels will prevent vascular access failure in hemodialysis patients, they added.

-Marv Ann Moon

Brief Summary of Prescribing Information (Nos. 1541, 1543, 1544, 3046, 7309, 7311) 03-5366-R24-Brf. Rev. July, 2004

 $\textbf{PREVACID}^{\circledR} \ (\textbf{lansoprazole}) \ \textbf{Delayed-Release} \ \textbf{Capsules}$

PREVACID® (lansoprazole) For Delayed-Release Oral Suspension

PREVACID® SoluTabTM (lansoprazole) Delayed-Release Orally

tegrating Tablets

HX ONIY
PREVACID Delayed-Release Capsules, PREVACID SoluTab Delayed-Release Orally Disintegrating Tablets and PREVACID For Delayed-Release Oral Suspension are indicated for:

Short-Term Treatment (4 weeks) of Active Duodenal Ulcer
H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
Triple Therapy: PREVACID/amoxicillin/clarithromycin
Dual Therapy: PREVACID/amoxicillin/clarithromycin or in whom resistance to clarithromycin is known or suspected.
Who are either altergic or indierant to clarithromycin or in whom resistance to clarithromycin is known or suspected.
Maintenance of Healed Duodenal Ulcers
Controlled Studies do not extend beyond 12 months.
Short-Term Treatment (up to 8 weeks) of Active Benign Gastric Ulcer
Healing of NSAID-Associated Gastric Ulcer
In patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.
Risk Reduction of NSAID-Associated Gastric Ulcer Delayed-Release Capsules, PREVACID SoluTab Delayed-Release Orally ng Tablets and PREVACID For Delayed-Release Oral Suspension are indicated

In patients with Continuor North User. Controlled Studies due not exterior depoind o weeks.

Risk Reduction of NSAID-Associated Gastric Ulcer
In patients with a history of a documented gastric ulcer who require the use of an NSAID.

Controlled studies did not extend beyond 12 weeks.

Controlled studies did not extend beyond 12 weeks.

Gastroesophageal Reflux Disease (GERD)

Short-Term Treatment of Symptomatic GERD

Short-Term Treatment (up to 8 weeks) of Erosive Esophagitis

For patients who do not heal with PREVACID for 8 weeks (5-10%), it may be helpful to give

an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis an

additional 8-week course of PREVACID may be considered.

Maintenance of Healing of Erosive Esophagitis

Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome

CONTRAINDICATIONS

NAMEDICALIUNS

ICID is contraindicated in patients with known hypersensitivity to any component of mulation of PREVACID.

the formulation of PREVACID.

Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin. Clarithromycin is contraindicated in patients with a known hypersensitivity to clarithromycin is contraindicated in patients with a known hypersensitivity to clarithromycin, is contraindicated. The macrolide antibiotics.

Concomitant administration of clarithromycin with cisapride, primozide, astemizole, or terfenadine is contraindicated. There have been post-marketing reports of drug interactions when clarithromycin and/or epthornogric and

CHARLIHRUMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES WHERE NO ALTERNATIVE THERAPY IS APPROPRIATE. IF PREGNANCY OCCURS WHILE TAKING CLARITHROMYCIN, THE PATIENT SHOULD BE APPRISED OF THE POTENTIAL HAZARD TO THE FETUS. (SEE WARNINGS IN PRESCRIBING INFORMATION FOR CLARITHROMYCIN.)

PSEUdomembranous collits has been reported with nearly all antibacterial agents, including clarithromycin and amoxicillin, and may range in severity from mild to liferatedening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been accurate the present of the present

overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of antibiotic-associated colitis:

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillim theyary. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been well-documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions who have experienced severe hypersensitivity reactions under the appropriate therapy instituted.

SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TERATMENT WITH PINEFHRINE OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATEO.

PRECAUTIONS

neneral
imptomatic response to therapy with lansoprazole does not preclude the presence of
stric malignancy.

gastric malignancy.

Information for Patients

PREVACID is available as a capsule, orally disintegrating tablet and oral suspension, and is available in 15 mg and 30 mg strengths. Directions for use specific to the route and available methods of administration for each of these dosage forms is presented below. PREVACID should be taken before eating. PREVACID products SHOULD NOT BE CRUSHED OR CHEWED.

enylketonurics: Contains Phenylalanine 2.5 mg per 15 mg Tablet and 5.1 mg per

30 mg Tablet.

Administration Options

1. PREVACID Delayed-Release Capsules

PREVACID Delayed-Release Capsules

PREVACID Delayed-Release Capsules should be swallowed whole.

Alternatively, for patients who have difficulty swallowing capsules, PREVACID DelayedRelease Capsules can be opened and administered as follows:

Open capsules

apsule: e intact granules on one tablespoon of either applesauce, ENSURE[®] pudding, cheese, yogurt or strained pears. PREVACID Delayed-Release Capsules may also be emptied into a small volume of either apple juice, orange juice or formato juice and administered as follows:

- Open capsule.

Sprinkle intact granules into a small volume of either apple juice, orange juice or tomato juice (60 mL – approximately 2 ounces).

- Mix briefly.
- Swallow mmediately.
- To ensure complete delivery of the dose, the plass should be rinsed with two or more volumes of luice and the contents swallowed immediately.

USE IN OTHER FOODS AND LIQUIDS HAS NOT BEEN STUDIED CLINICALLY AND IS THEREFORE NOT RECOMMENDED.

2. PREVACID SoluTab Delayed-Release Orally Disintegrating Tablets
PREVACID SoluTab should not be chewed. Place the tablet on the tongue and allow it to
disintegrate, with or without water, until the particles can be swallowed. The tablet typically
disintegrates in less than 1 minute.
Alternatively, for children or other patients who have difficulty swallowing tablets,
PREVACID SoluTab can be delivered in two different ways.
PREVACID SoluTab - Oral Syringe
FOR administration via oral syringe, PREVACID SoluTab can be administered as follows:
Place a 15 mg tablet in oral syringe and draw up approximately 4 mL of water, or place a
30 mg tablet in oral syringe and draw up approximately 4 mL of water.

Shake gently to allow for a quick dispersal.

After the tablet has dispersed, administer the contents within 15 minutes.

Refill the syringe with approximately 2 mL (5 mL for the 30 mg tablet) of water, shake gently, and administer any remaining contents.

PREVACID SoluTab – Nasogastric Tube Administration (≥ 8 French) For administration via a nasogastric tube, PREVACID SoluTab can be administered as

follows:

Place a 15 mg tablet in a syringe and draw up 4 mL of water, or place a 30 mg tablet in a syringe and draw up 10 mL of water.

Stake gently to allow for a quick dispersal.

After the tablet has dispersed, inject through the nasogastric tube into the stomach within 15 minutes.

The induces have also become a support of the induces of the induc tube.
3. PREVACID for Delayed-Release Oral Suspension
REVACID for Delayed-Release Oral Suspension should be administered as follows:
Open peoplet:

Upen packet.
To prepare a dose, empty the packet contents into a container containing 2 tablespoons of WATER. DO NOT USE OTHER LIQUIDS OR FOODS.

whiten. But Not located their builds of Pools.

• If any material remains after drinking, add more water, stir, and drink immediately.

• This product should not be given through enteral administration tubes.

• This product snould not be given through enteral administration tubes.

Drug Interactions

Lansoprazole is metabolized through the cytochrome P₄₅₀ system, specifically through the CYP3A and CYP2C19 isozymes. Studies have shown that lansoprazole does not have clinically significant interactions with other drugs metabolized by the cytochrome P₄₅₀ system, such as warfarin, antipyrine, indomethacin, ibuproten, phentytion, prorandol, prednisone, diazepam, or clarithromycin in healthy subjects. These compounds are metabolized through various cytochrome P₄₅₀ isozymes including CYP1A2, CYP2C9, CYP2C19, CYP2C

seen. Because of the small magnitude and the direction of the effect on theophyllic declarance, this interaction is unlikely to be of clinical concern. Nonetheless, individual patients may require additional titration of their theophylline dosage when lansoprazole is started or stopped to ensure clinically effective blood levels.

In a study of healthy subjects neither the pharmacokinetics of warrarin enantiomers no prothrombin time were affected following single or multiple 60 mg doses of lansoprazole. However, there have been reports of increased International Normalized Ratio (INR) and prothrombin time in patients receiving proton pump inhibitors, including lansoprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin concomitantly. Increases in INR and prothrombin time. Lansoprazole has also been shown to have no clinically significant interaction with amoxicillin. In a single-dose crossover study examining lansoprazole 30 mg and omeprazole 20 mg each administered alone and concomitantly with surcaffate 1 gram, absorption of the proton pump inhibitors and delayed and their bioavailability was reduced by 17% and 16%, respectively, when administered concomitantly with surcaffate. In clinical trials, antacids were administered concomitantly with PREVACID Delayed-Release Capsules; this did not interfere with its effect.

Lansoprazole causes profound and long-lasting inhibition of gastric acid secretion; therefore, it is theoretically possible that lansoprazole may interfere with the absorption of drugs where gastric pf1 is an important determinant of bioavailability (e.g., ketoconazole, amplicially esters, iron salts, digoxin).

Carcinogenesis, Mutagenesis, Impairment of Fertility

In two 24-month carcinogenicity studies, Sprague-Dawley rats were treated orally with doses of 5 to 150 mg/kg/day, about 1 to 40 times the exposure on a body surface (mg/m²) significant interstitial cell adenoma.

body surface area).

Lansoprazole was not genotoxic in the Ames test, the *ex vivo* rat hepatocyte unscheduled DNA synthesis (UDS) test, the *in vivo* mouse micronucleus test or the rat bone marrow cell chromosomal aberration test. It was positive in *in vitro* human lymphocyte chromosomal

chromosomal aberration test. It was positive in *in vitro* human lymphocyte chromosomal aberration assays. Lansoprazole at oral doses up to 150 mg/kg/day (40 times the recommended human dose based on body surface area) was found to have no effect on fertility and reproductive performance of male and female rats.

Pregnancy Tendoponic Effects.

Pregnancy Category B

Tregianity Gategory B Lansoprazole Teratology studies have been performed in pregnant rats at oral doses up to 150 mg/kg/day (40 times the recommended human dose based on body surface area) and pregnant rabbits at oral doses up to 30 mg/kg/day (16 times the recommended human dose based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to lansoprazole. There are, however, no adequate or well-controlled studies in pregnant women. Because iansoprazole, and have revealed no evidence of impaired fertility or harm to the fetus due to anasoprazole area, however, no adequate or well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Pregnancy Category C

Clarifromycin

See WARNIMES (See

ithromycin **WARNINGS** (above) and full prescribing information for clarithromycin before using in

drug, taking into account are important to the Prediatric Use.

The safety and effectiveness of PREVACID have been established in pediatric patients 1 to 17 years of age for short-term treatment of symptomatic GERD and erosive esophagitis. Use of PREVACID in this population is supported by evidence from adequate and well-controlled studies of PREVACID in adults with additional chilical, pharmacoximatic studies performed in pediatric patients. The adverse events profile in pediatric patients is similar to that of adults. There were no adverse events reported in U.S. pediatric patients is similar to that of adults. There were no adverse events reported clinical studies that were not previously observed in adults. The safety and effectives PREVACID in patients <1 year of age have not been established.

1.1 11 year of age.

PREVACID in patients <1 year of age have not been established.

10 11 years of age

The pediatric safety of PREVACID Delayed-Release Capsules has been assessed in 6 pediatric patients aged 1 to 11 years of age, 0f the 66 patients with GERD 85% (56/66) took PREVACID for 8 weeks and 15% (10/66) took it for 12 weeks.

The most frequently reported (2 or more patients) treatment-related adverse events in patients 1 to 11 years of age (M-65) were constipation (5%) and headache (3%).

patients 1 to 11 years of age (re-po) were consuparon (evg and necessary). The safety of PREVACID Delayed-Release Capsules has been assessed in these Radolescent patients with GERD, 6% (5,687) took PREVACID for 6- weeks, 39% (81/87) for 6-10 weeks, and 1% (1/87) for 1-0 weeks. The most frequently reported (at least 3%) terminent-related daverse events in these patients were headache (7%), abdominal pain (5%), nausea (3%) and dizziness (3%). Treatment-related daverse events in these patients were headache (7%), abdominal pain (5%), nausea (3%) and dizziness (3%). Treatment-related davies, reported in this study by 3 adolescent patients with noncrosive GERD, who had dizziness concurrently with other events (such as migraine, dyspnea, and vomiting). Here in Winnen

Use in Geriatric Patients
Ulcer healing rates in elderly patients are similar to those in a younger age group. The

need not be altered for a particular indication.

ADVERSE REACTIONS

Clinical

Worldwide, over 10,000 patients have been treated with lansoprazole in Phase 2-3 clinical
trials involving various dosages and durations of treatment. The adverse reaction profiles for
PREVACID Delayed-Release Capsules and PREVACID for Delayed-Release Oral Suspension
are similar. In general, lansoprazole treatment has been well-tolerated in both short-rem and long-term trials.

The following adverse events were reported by the treating physician to have a possible or
probable relationship to drug in 1% or more of PREVACID-treated patients and acquester rate in PREVACID-treated patients. Incidence of Possibly or Probably

Treatment-Related Adverse Events in Short-Term, Placebo-Controlled Studies

Treatment-Related Adverse Events in Short-Term, Placebo-Controlled Studies		
	PREVACID	Placebo
	(N= 2768)	(N= 1023)
Body System/Adverse Event	%	%
Body as a Whole		
Abdominal Pain	2.1	1.2
Digestive System		
Constipation	1.0	0.4
Diarrhea	3.8	2.3
Nausea	1.3	1.2

aussea dache was also seen at greater than 1% incidence but was more common on placebo. Incidence of diarrhea was similar between patients who received placebo and patients or received lansoprazole 15 mg and 30 mg, but higher in the patients who received soprazole 60 mg (2.9%, t.4%, 4.2%, and 7.4%, respectively), en most commonly reported possibly or probably treatment-related adverse event during

The most commonly reported possibly or probably treatment-felated adverse event during naintenance therapy was diarrhea. In the risk reduction study of PREVACID for NSAID-associated gastric ulcers, the incidence of diarrhea for patients treated with PREVACID was 5%, misoprostol 22%, and placebo 3%. Additional adverse experiences occurring in <1% of patients or subjects in domestic trials re shown below. Refer to Postmarketing for adverse reactions occurring since the drug as marketed.

Additional adverse experiences occurring in <1% of patients or subjects in domestic trials are shown below. Refer to Postmarketing for adverse reactions occurring since the drug was marketed.

Body as a Whole – abdomen enlarged, allergic reaction, asthenia, back pain, candidiasis, carcinoma, chest pain (not otherwise specified), chilis, edema, fever, flu syndrome, halitosis, infection (not otherwise specified), malaise, neck pain, neck rigidity, pain, pelvic pain; cardiovascular scidentificers system – angina, arrhythmia, bradycardia, cerebrovascular accidentificerebral infarction, hypertension/hypotension, migraine, myocardial infarction, palpitations, shock (circulatory lature), syroope, tachycardia, expediadial provinovascular accidentificerebral infarction, phypertension/hypotension, migraine, myocardial infarction, palpitations, shock (circulatory lature), syroope, tachycardia, exodidiation; Diegetive System – ahonormal stools, anorexia, bezoar, cardiospasm, choleithiasis, colitis, dry mouth, dyspepsia, dysphagia, entertitis, eructation, esophageal stensoris, sophageal ulcer, esophagitis, fecal discoloration, flatulence, gastric nodules/fundic gland polyps, gastriits, gastroenteritis, guartsometheritis, g

erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (some fatal); Special Senses: speech disorder, Urlognalial System - urinary retention.

Combination Therapy with Amoxicillin and Clarithromycin
In clinical trials using combination therapy with PREVACID plus amoxicillin and carithromycin, and PREVACID plus amoxicillin, no adverse reactions peculiar to these drug combinations were observed. Adverse reactions that have occurred have been limited to those that had been previously reported with PREVACID, amoxicillin, or clarithromycin.

Triple Therapy: PREVACID/amoxicillin/clarithromycin
The most frequently reported adverse events for patients who received triple therapy for 14 days were diarrhea (7%), headache (6%), and taste perversion (5%). There were no statistically significant differences in the frequency of reported adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events between the 10- and 14-day triple therapy regimens. No treatment-emergent adverse events were observed at significantly higher rates with PREVACID Li.d. plus amoxicillin Li.d. dual therapy were diarrhea (8%) and headache (7%). No treatment-emergent adverse events were observed at significantly higher rates with PREVACID Li.d. plus amoxicillin Li.d. dual therapy with an with PREVACID alone.

For more information on adverse reactions with amoxicillin or clarithromycin, refer to their package intests, ADVERSE REACTIONS sections.

package inserts, ADVENSE REACTIONS Sections. Laboratory Values The following changes in laboratory parameters for lansoprazole were reported as adverse

events:
Abnormal liver function tests, increased SGOT (AST), increased SGPT (ALT), increased
recatatinie, increased alkaline phosphatase, increased globulins, increased GGTP,
increased/decreased/abnormal WBC, abnormal AG ratio, abnormal ABC, bilirubinemia,
cosinophila, hyperlipemia, increased/decreased electrolytes, increased/decreased
cholesterol, increased gloucocorticoids, increased LDH, increased/decreased/abnormal
patelets, and increased gastrin levels. Urine abnormalities such as abuminuria, glycosuria,
and hematuria were also reported. Additional isolated laboratory abnormalities were
recorded.

in the placebo controlled studies, when SGOT (AST) and SGPT (ALT) were evaluated, 0.4% (41/978) placebo patients and 0.4% (11/2677) lansoprazole patients had enzyme elevations greater than three times the upper limit of normal range at the final treatment visit. None of these lansoprazole patients reported jaundice at any time during the study. In clinical trials using combination therapy with PREVACID plus amoxicillin and clarithromycin, and PREVACID plus amoxicillin, no increased laboratory abnormalities particular to these drug combinations were observed.

parucurar to triese grug combinations were observed.
For more information on laboratory value changes with amoxicillin or clarithromycin, refer of their package inserts, ADVERSE REACTIONS section.

OVERDOSACE

Oral doses up to 5000 mg/kg in rats (approximately 1300 times the recommended human dose based on body surface area) and mice (about 675.7 times the recommended human dose based on body surface area) did not produce deaths or any clinical signs. Lansoprazole is not removed from the circulation by hemodialysis, in one reported case of overdose, the patient consumed 600 mg of lansoprazole with no adverse reaction. Distributed by
TAP Pharmaceuticals Inc.
Lake Forest, IL 60045, U.S.A.

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For more detailed information, see full prescribing information or contact TAP Medical Information at 1-800-622-2011.

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